No. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,

Petitioner,

vs.

MEDTRONIC, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF AMICUS CURIAE TELECTRONICS, INC. IN SUPPORT OF THE RESPONDENT

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QUESTION PRESENTED

Does 35 U.S.C. Section 271(e)(1) apply to medical devices as well as to drugs and veterinary biological products?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

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INTEREST OF AMICUS

Telectronics, Inc. ("Telectronics") respectfully submits this brief as *amicus curiae* in support of the position of Respondent Medtronic, Inc. ("Medtronic"). Counsel for Petitioner Eli Lilly and Company ("Lilly") and for Medtronic have both consented in writing to the filing of this brief.

Telectronics has an interest in this proceeding since Telectronics is a plaintiff in a declaratory judgment action now pending before the United States District Court for the District of Colorado entitled "Telectronics, Inc. v. Eli Lilly & Company, Inc. and Cardiac Pacemakers, Inc.", Civil Action No. 88-M-1815. Telectronics has asserted in that action that it has not infringed U.S. Patent No. Re. 27,757 ("the '757 patent"),

the same patent which has been asserted by Lilly in the litigation with Medtronic now before this Court. Lilly has alleged, by way of counterclaim in the Colorado action, that a medical device developed by Telectronics infringes the '757 patent, despite the fact that this device is still in a non-commercial clinical testing program directed to obtaining the required premarket approval from the Food and Drug Administration.

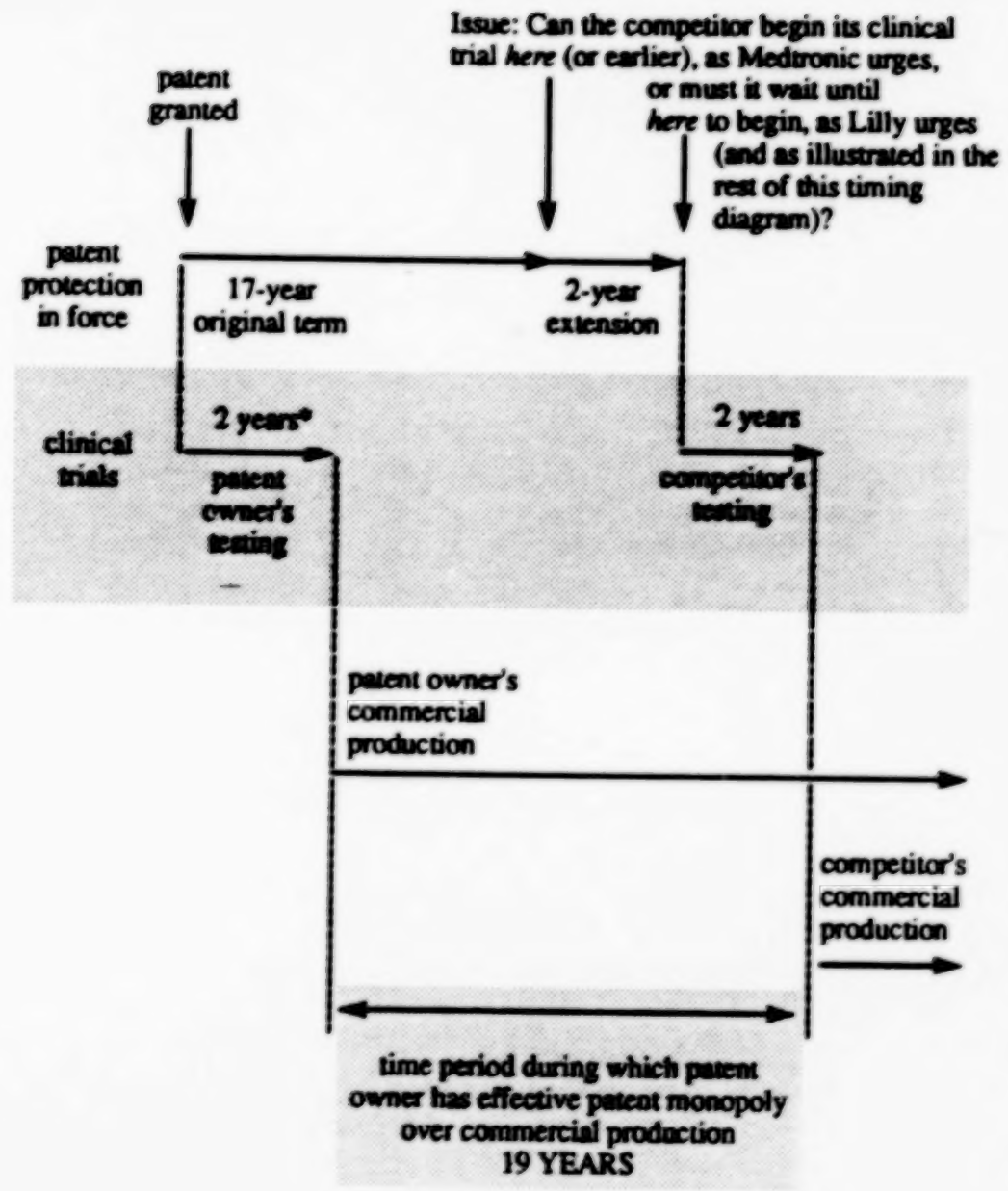
Telectronics therefore has an interest in the decision of this Court on the issue of whether or not the Section 271(e)(1) exemption for FDA testing is applicable to medical devices.

SUMMARY OF ARGUMENT

Lilly obtained an extension, under 35 U.S.C. Section 156, extending the "life" of its patent monopoly for two years. Section 271(e)(1) must be read in conjunction with the extension provisions of 35 U.S.C. Section 156. Congress made it clear that there were to be no other *de facto* extensions of the patent monopoly. Only by construing Section 271(e)(1) to encompass medical devices will Congress' intent be realized.

ARGUMENT

A picture is worth a thousand words. The '757 patent would normally have expired in October, 1988, but Lilly obtained a two-year extension of the patent, pursuant to 35 U.S.C. Section 156. If time is measured from left to right, the following sketch depicts the issue before the Court and, because it is based on Lilly's view, it shows that the patent owner's effective monopoly (during which it is the only party capable of commercial production) is 19 years:



* The patent owner's testing can begin even before the patent issues. If it does, the effective patent monopoly is even longer.

sought by petitioner here, nor to prevent improvements being made by others upon the patented invention during that time.

The need to allow certain uses of the patented invention in order to carry out the Constitutional policy was recognized very early on by the courts in the so-called "experimental use exception" to infringement. As originally enunciated by Justice Story in 1813, this exception provided a careful balance between the public interest and the reward given to the inventor. Unfortunately, more recent decisions have narrowed the exception. In particular, the benefit of the exception has effectively been denied to any actual or potential competitor, the only people who are likely to have the funds or incentive to develop improvements. The balance has been shifted away from the advancement of knowledge for the public benefit, and towards the interests of the individual patentee.

Congress, in enacting 35 U.S.C. § 271(e)(1), recognized in part the need to stimulate public innovation and research, and established an exception to infringement for FDA testing. The plain meaning of that statute, and its legislative history, establishes that it extends to the FDA testing of all medical products, devices as well as drugs. However, the statute fails to specifically deal with, in a positive or negative sense, the broader scope of the traditional experimental use exception. Further, petitioner and its amici would now have that section substantially limited by judicial legislation to exclude from its infringement exemption all medical products but drugs. This would clearly not be in the public interest.

ARGUMENT

Amici Acadamic Research Centers respectfully request the Court to maintain the balance in its proper place, and confirm an experimental use exception that

permits research for the accumulation of knowledge and scientific data and allows competitive testing, both FDA-related or otherwise, regardless of whether there is an ultimate commercial motivation behind these activities.

Petitioner Lilly and its supporting amici are requesting that the Court substantially expand the rights of medical device patentees, enabling a patentee to prevent others from beginning even FDA-regulated testing for new devices until after patent expiration. The direct result of such an alteration in the law would be to grant medical device patentees a significant *de facto* extension, above and beyond any statutory extension, effectively preventing the availability of new technology until the completion of that testing several years after patent expiration. Such a judicially legislated expansion could affect timely, leading-edge research and development on medical devices in the United States, particularly in the university arena. This was not the intent of Congress when it enacted 35 U.S.C. § 271(e)(1), nor is it in keeping with the original constitutional intent behind the present U.S. patent system.

I. THE PATENT SYSTEM WAS INTENDED TO INCREASE THE STORE OF PUBLIC KNOWLEDGE AND TO STIMULATE DOMESTIC INNOVATION

A patent gives its owner ". . . the right to exclude others from making, using, or selling the invention throughout the United States. . ." for a term of seventeen years. 35 U.S.C. § 154. These or similar words have appeared in every United States patent statute since the original Patent Act of 1793. Congress has never provided a statutory definition of these terms, leaving their scope to judicial interpretation. *Roche Prods., Inc. v. Bolar Pharmaceuticals Co.,* 733 F.2d 858 (Fed. Cir.), *cert. denied,* 496 U.S. 856 (1984).

On its face, the language used by Congress forbids all uses of the patented invention. However, the early

courts recognized that prohibiting certain uses could be contrary to the policy underlying the patent system.

> [I]t is true that the words used, even in their literal sense, are the primary, and ordinarily the most reliable source of interpreting the meaning of any writing; be it a statute, a contract, or anything else. But it is one of the surest indexes of a mature and developed jurisprudence not to make a fortess out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning.

Cabell v. Markham, 148 F.2d 737, 739 (2d. Cir.) (Judge Learned Hand), *aff'd,* 326 U.S. 404 (1945). The term "use" in the patent statutes has never been extended to every possible use. *Roche,* 733 F.2d at 861. Examination of the Constitutional principles of the patent system shows that an effective exception for research is vitally necessary to the public interest.

This Court has long recognized the principles underlying the United States patent system: "This court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is 'to promote the progress of science and the useful arts.' (Constitution, Art. I, § 8)." *Motion Picture Patents Co. v. Universal Film Mfg.,* 243 U.S. 502, 512 (1917).[2]

In its most recent decision on patent matters, *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.,* ___ U.S. ___, ___, 109 S. Ct. 971, 975 (1989), Justice O'Connor, writing for the unanimous Court, stated:

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2. *See, also, Shaw v. Cooper,* 32 U.S. 292, 314-16 (1833); *U.S. v. Masonite Corp.,* 316 U.S. 265, 280 (1942); *Sears, Roebuck & Co. v. Stiffel Co.,* 376 U.S. 225, 230-31 (1964); *Deepsouth Packing Co. v. Laitram Corp.,* 406 U.S. 518, 530-31 (1972).

> The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the "Progress of Science and the Useful Arts." . . .
>
> • • •
>
> From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.

It is clear that the patent statutes must be interpreted so that the interest of the patentee is not overly protected to the public detriment.[3]

The primary means of furthering the constitutional purpose of promoting the progress of science and useful arts is by encouraging disclosure of information that adds to the public store of available knowledge.

> When a patent is granted and the information contained in it is circulated to the general public and those especially skilled in the trade, such additions to the general store of knowledge are of such importance to the public weal that the Federal Government is willing to pay the high price of 17 years of exclusive use for its disclosure, which disclosure, it is assumed, will stimulate ideas and the eventual development of further significant advances in the art.

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3. This principle is at the root of the Anglo-American patent jurisprudence. The English Statute of Monopolies, 1623, 21 Jac., c.3, § 14, which exempted letters patent from the general prohibition of monopolies, also contained the limitation that letters patent were not to be granted if they would be contrary to the law, "mischievous to the State, by raising prices of Commodities at Home or Hurt of Trade, or generally inconvenient."

Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974). However, if this information cannot be used by the public even for research purposes, then very little benefit would be obtained in return for that extensive period of exclusivity, and that period would be effectively lengthened. It is, therefore, inconsistent with patent system policy to allow the patent owner to prevent all use of the information disclosed in the patent until the patent expires.[4] This is particularly true of uses that do not appropriate any of the financial rewards of exclusivity.

The increase in public knowledge encouraged by the patent system is not for pure intellectual satisfaction. It is to stimulate the search for further knowledge and the development of improved technology. It is only through such research and development that progress in science and the useful arts is assured. This research and development in a free market economy is spurred on by the need to compete with the patentee.[5] If the preliminary research and testing necessary to such competition were made impossible during the patent term, technological progress would slow to a snail's pace. This is not what the founding fathers intended.

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4. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 219 (1987), comments that:

> If the public had absolutely no right to make, use, or sell the patented invention until the end of the patent term, it would be somewhat puzzling to require that the patentee give the public an enabling disclosure at the *beginning* of the term. The requirement of early disclosure suggests that certain uses of patented inventions during the patent term do not constitute patent infringement. (Emphasis in original.)

5. A practical description of the effect of a strong patent system in a competitive market in spurring improvements and new developments, given by the late Charles E. Lucke, professor and head of the Mechanical Engineering Department of the School of Engineering of Columbia University, can be found in 1 LIPSCOMB'S WALKER ON PATENTS, § 1:8, 55-56 (3rd ed. 1984).

II. PREVENTING TESTING PRIOR TO PATENT EXPIRATION WILL UNDERMINE RESEARCH EFFORTS ON MEDICAL DEVICES IN THE UNITED STATES

Teaching hospitals, in conjunction with their affiliated universities, serve a critical and indispensable role in domestic research and public health. For all practical purposes, university hospitals are the only places *in the United States* where clinical testing of new medical products can be conducted. Such necessary clinical testing should not be unreasonably stifled to the detriment of the public by judicially legislated expansion of patent rights. Yet, this is exactly what petitioner requests here. Petitioner and its amici claim, without any record support, that the decision below will significantly impede the availability of new medical products and discourage innovation in the medical product field. In fact, just the opposite is true. It is the adoption of petitioner's view that would chill medical device innovation.

As justification for its view, petitioner has repeatedly stated that Medtronic and other medical product developers are free to take their clinical testing overseas and, thereafter, to use the results of that testing to obtain U.S. FDA approval.[6] It is just this unfortunate scenario that *will* occur, however, should the exemption of section 271(e)(1) be withdrawn from non-drug medical products, and it is precisely this scenario that should be prevented. Substantial harm to U.S. research and development efforts will result from adoption of petitioner's

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6. Indeed, this was also one of Lilly's principal justifications in support of maintaining an injunction against Medtronic prohibiting testing in the United States. *See, e.g.*, Lilly's Application To Stay Mandate Of The Federal Circuit, filed in this Court July 21, 1989, pp.21, and 24-25; and Lilly's Reapplication For An Order To Recall And Stay The Mandate, filed here October 20, 1989, pp.3, 6, and 9.

position, irretrievably stifling U.S. innovation in favor of foreign research and testing.

The harm results from the fact that in the university environment, and particularly in the medical products field, participating in the development of the latest technology is critical. Leading researchers are drawn to locations where they can work on cutting edge technologies. Petitioner would send those innovators overseas.

There is no disagreement that FDA experimentation involving drugs is exempt from infringement. But the drug field is more static than the medical device field. Once a particular drug is found to be effective in a particular application, there is little incentive to develop other drugs to accomplish the same result. Thus, the commercial lifespan of a drug can continue indefinitely. It is quite common for a once-patented drug (for example, aspirin) to remain in strong demand well after the expiration of the patent. Indeed, the very existence of the generic drug industry attests to that fact.

Medical device technology, on the other hand, is constantly changing, providing newer, more precise, and more reliable devices to supplant older ones. Once it is the law that these newer medical devices can be experimentally evaluated and clinically tested in foreign countries years earlier than in the United States, however, those who perform basic research on new products will naturally be drawn away from the United States and towards overseas testing facilities.

Although preliminary studies may remain possible at U.S. institutions, actual testing on animals and humans will not. However, these tests are key to ultimate advancement in the medical products field, because only animal and human testing can determine whether or not a particular device is safe and effective and only such tests can satisfy the FDA. The United States has the finest clinicians in the world. United States citizens deserve to have those clinicians evaluate new products at the earliest possible time.

Congress did not intend to stifle such early evaluation when it enacted section 271(e)(1).

Moreover, while university hospitals, as sites for clinical testing, presently employ many of the most innovative doctors and scientists, their work is enhanced by significant corporate sponsorship. Although the universities act as spawning grounds for significant new ideas, those ideas typically cannot be developed to the point of useful application to humans without the technical and economic resources, and practical knowledge, maintained within the commercial community. But again, if overseas testing of medical products is given a multi-year lead time, the realities of the marketplace will force corporate sponsorship to shift away from U.S. universities and towards support of foreign universities and facilities. In order to effectively enter a post-patent market, U.S. (as well as foreign) manufacturers will be compelled to spend their research dollars abroad. Once U.S. manufacturers have committed their efforts overseas, moving people and developing laboratories, there is a serious likelihood that those operations will not be returned, even after the relevent U.S. patents expire.

This is also not what Congress intended when it enacted section 271(e)(1).

The disclosure provisions of the patent laws are of little benefit in promoting U.S. scientific progress if the patents themselves, because of regulatory delays, preclude the entry of competing technology far beyond their expiration dates. The United States cannot afford to lose its lead in the medical device field simply because certain patentees desire to expand their patent rights beyond the bounds of the law and the intentions of Congress.

III. A BROAD INTERPRETATION OF SECTION 271(e)(1) IS IN KEEPING WITH THE TRADITIONAL EXPERIMENTAL USE EXCEPTION TO INFRINGEMENT

Experimental use of patented technology for the development and evaluation of improved medical devices should not be infringement even under the traditional experimental use doctrine. To limit that doctrine to only those experiments done for non-commercial purposes is to ignore the reality of modern university research. Even testing done for purely scientific purposes may be commercially motivated, and the data may represent an asset to the corporate sponsor of the research, but such testing must be recognized for its primarily experimental purpose and should not be precluded by a patent. Modern university research is no less beneficial to the public simply because it has an ultimate commercial objective or a corporate affiliation.

A. The History Of The Experimental Use Exception

The origin of an experimental use exception to the patentee's exclusive rights can be traced back to *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600). Supreme Court Justice Story, sitting as a Circuit Judge, was deciding a motion for a new trial in a patent case based on objections to a number of directions given to the jury. One of the directions objected to was that "the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right. . . ." Justice Story said of the direction:

> [I]t was adopted by the court from the consideration that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.

Id., 29 F. Cas. at 1121. (In that period, science was generally called "natural philosophy," so by "philosophical experiments" the Justice almost certainly meant what we would call scientific experiments.) Later the same year, Justice Story returned to the same theme in *Sawin v. Guild,* 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391):

> This court has already had occasion to consider the clause in question, and upon mature deliberation, it has held that the making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification. Whittemore v. Cutter [Case No. 17,600]. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Over the ensuing 175 years, this doctrine has been sporadically referred to, sometimes critically and sometimes approvingly. It has rarely been applied to excuse infringement.[7] Despite these later references, however, the clearest expositions of the doctrine remain the opinions of Justice Story.

B. Section 271(e)(1) Reflects the Policy Behind The Experimental Use Exception

The realities of modern research and development were recognized by Judge Wexler of the Eastern District

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7. The case law is reviewed and commented on by Hantman, *Experimental Use as an Exception to Patent Infringement,* 67 J. PAT. OFF. SOC'Y 617 (1985), and Israelson, *Making, Using And Selling Without Infringing: An Examination Of 35 U.S.C. Section 271(e) And The Experimental Use Exception To Patent Infringement,* 16 AM. INTELL. PROP. L.A.Q.J. 457 (1989).

of New York in *Roche Prods. Inc. v. Bolar Pharmaceuticals Co.*, 572 F. Supp. 255 (E.D.N.Y. 1983), *rev'd*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), the original district court case ultimately leading to the enactment of section 271(e)(1):

> Bolar's experimentation cannot be classified as merely for amusement or philosophical gratification. At the same time, it cannot be connected with any act of competition or profit during the term of the patent in either domestic or foreign markets. Its experimentation is commercial preparation of a non-production nature for post-expiration competition. In analogous cases this has been held a non-infringing use.

Id., 572 F. Supp. at 257. Generic manufacturer Bolar had begun using a drug patented by Roche to conduct the FDA testing required to begin marketing upon the patent's expiration. Bolar argued that to prohibit FDA testing until after patent expiration would result in a *de facto* extension of that patent for several years, until Bolar could complete all of the required testing, thereby delaying the availability of the generic substitute to the public. Roche countered that it, too, had been required to conduct extensive FDA testing, and that it was, in essence, entitled to such a *de facto* extension as compensation for its lost ability to market during its patent life. The district court attempted to balance the interests of the patentee in being free of competition during the patent term with those of the public in encouraging research activity that will enhance scientific understanding. Judge Wexler reviewed the case law, recognized the limits of the patent right, and found that Bolar's testing constituted experimental use.

> [T]he court cannot find a basis for holding that Bolar's limited experimental use of flurazepam hcl would constitute infringement. First, Bolar realizes

> no benefit during the term of the patent; its activities are in no way connected with current manufacture or sale here or abroad. Nor do its activities lessen Roche's profits during the patent's term. Second, post-expiration delay in competition unintentionally imposed by FDA regulation is not a right or benefit granted by the patent law.

Id., 572 F. Supp. at 258.

On appeal, the Federal Circuit focused only on the ultimate commercial objective of Bolar, regardless of whether that benefit was to be realized during the patent term, reversed the district court, and held that Bolar's experimental testing was an infringement of the Roche patent. At the time of the decision, the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "PTR Act") was pending before Congress, although without any section corresponding to section 271(e). As a result, the Federal Circuit indicated that Congress could best decide how to balance the competing interests represented by the parties then before it. *Roche*, 733 F.2d at 865.

Thereafter, through the passage of the PTR Act with section 271(e), Congress balanced those interests and substantially remedied the problems resulting from regulatory delays. The remedy, however, is not limited to drugs. Section 271(e)(1) as passed reflects a recognition of the modern realities of medical research, balancing the regulatory delay with extended patent rights while concurrently allowing for certain pre-expiration experimental use as had been recognized by Judge Wexler.

C. The Experimental Use Exception Should Be Broadly Construed In Order To Foster Innovation

The importance of, and ultimate commercial motivation for, much basic research carried on in universities has been very evident in recent years. For example, the

basic techniques on which the rapidly growing biotechnology industry is built originated in university research facilities and were patented by those universities. Another development that has recently come out of university research, for example, and that could have enormous potential for commercial exploitation are high temperature superconductors, which are the subject of pending patent applications. Indeed, Congress has encouraged universities to patent and commercially license inventions made in the course of government funded research.[8]

Except as now overruled with respect to FDA testing of medical products by the enactment of section 271(e), however, the Federal Circuit in *Roche* effectively stated that any commercially-motivated experimental activity would be an infringement regardless of whether or not it interfered with business interests of the patentee in exploiting his invention. Because the complex research demanded by modern technology almost always has a commercial or business objective, albeit remote at times, virtually all research by commercial enterprises can now be enjoined by owners of dominant patents.

The Federal Circuit in *Roche* apparently thought that Justice Story's formulation of the exception was limited to "dilettante affairs." *Id.*, 733 F.2d at 863. This seems inconsistent, however, both with what the learned Justice actually said, and with the understanding of the exception expressed by other leading authorities.[9] The practical effect of adhering to the

8. Under the 1980 Patent and Trademark Act Amendments, universities must report any potentially patentable invention to the funding agency within a certain time, and may elect to retain most rights to the invention provided a patent application is promptly filed. Therefore, Congress has clearly encouraged the commercial exploitation of university research.

9. *See, e.g.*, 3 ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS, § 898 (1890):

limitations set out in the *Roche* decision would be to tip the balance too far in favor of the patentee. It would give the patent owner too much power to stifle research and development of improvements and it would make designing around a patent a seriously risky business. Such a sterile view of experimental use would provide an affirmative discouragement to innovation and should be directly refuted.

The law should be interpreted so that primary importance is given to the public interest in promoting the progress of science and technology. Among other things, this involves increasing the store of available public knowledge, encouraging scientific research and the development of improved technology, and weeding out invalid patents. On the other hand, inventors should receive the promised reward, the right to be free from competition in the practice of the invention. *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944).

The experimental use exception as set out by Justice Story maintains a fair balance between these two factors. The exception, as carried out by the exemption of section 271(e)(1), should cover every use of the patented invention that is either for research into the nature of the invention itself or for testing the sufficiency of the patent disclosure, provided that neither is done in order to use the invention itself for profit, depriving the patentee of

> [A]cts of infringement must attack the right of the patentee to these emoluments, and either turn them aside into other channels or prevent them from accruing in favor of any one. . . . But the manufacture or the use of the invention may be intended only for other purposes, and produce no pecuniary result. Thus, where it is made or used as an experiment whether for the gratification of scientific tests, or for curiosity, or for amusement, the interests of the patentee are not antagonized. . . .

his lawful rewards.[10]

IV. Reversal Of The Federal Circuit Decision Will Undermine Rather Than Enhance Research, Development, And Innovation

Petitioner and its amicus partners devote considerable time to the unsupported argument that the Federal Circuit's interpretation of section 271(e)(1) will destroy the incentive of device patentees to innovate. They provide no evidence, however, that medical device developers will be dissuaded from investing in research out of fear that new technology will become available some seventeen to twenty-two years later, after their patents, many of which will have been statutorily extended, expire. There is no such evidence because the Federal Circuit's decision does not lead to any of this imaginary harm.

To the contrary, the decision below fosters innovation. It encourages the original patent holder to innovate further during the patent term if he wishes to maintain, or at least share in, the technological lead. It permits basic experimentation and research by others to begin at a reasonable time into the patent term without the fear that a huge damage award, such as was requested by

10. In the context of section 271(e)(1), existing FDA regulations comport with the traditional experimental use exception while recognizing the realities of modern research. They are designed to ensure that all regulatory testing is limited, experimental, and non-commercial. The FDA prohibits, as improper commercialization, test marketing of a clinical device; charging investigators a price greater than necessary to recover costs of manufacturing, research, development, and handling; and unduly prolonging any investigation. 21 C.F.R. § 812.7. Generally, when the FDA does approve a clinical test plan, it specifies the locations where the investigation may take place, and sets a specific limit on the total number of products or tests that may be run under the IDE (Joint Appendix, pp.91-92). Accordingly, FDA guidelines and procedures are already in place to protect the legitimate rights of patentees by ensuring that regulatory testing is not commercialization.

petitioner here, will result. The deterrent effect of such an award on corporate sponsors would dry up their contributions to academic consultants and research in this country, providing further incentive for the transfer of these corporate research funds overseas.

It is the narrow interpretation of section 271(e)(1) advanced by petitioner that will stifle creativity and reward imitation rather than innovation. If the Federal Circuit decision is reversed, researchers who would otherwise develop new medical devices during the final years of a patent's statutory term will receive less under the patent laws than do drug copiers.[11] While generic drug manufacturers can now conduct bioequivalency testing prior to the end of a patent term so as to copy a product already available to the public, device researchers who would otherwise advance the technology in the medical field will be required to await the expiration of an extended patent term. It may not reasonably be assumed that Congress would use the patent laws, whose purpose is to increase the store of public knowledge, *Shaw v. Cooper*, 32 U.S. 292, 314-16 (1833), to encourage copying while delaying technical advances.

In all events, petitioner's major premise for its erosion-of-rights arguments (Petitioner's Brief, pp.28-33) is faulty. Petitioner's argument — that regulatory testing of devices by others is actually marketing and commercialization in disguise, thus discouraging innovation by patent holders — is squarely at odds with the determination made by Congress as to statutory patent term extension. As the reason for its enactment of 35 U.S.C. § 156, Congress determined that the regulatory testing required of certain products, devices as well as

11. Since medical devices cannot be approved on an expedited basis, as can generic drugs, there is no reason for a device developer to provide a "me-too" product. Rather, since all medical devices require a full set of pre-clinical and FDA-clinical tests, researchers are more interested in developing completely new technology.

drugs, effectively prevented the patentee of such products from marketing them. H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. I, at 17, *reprinted in* 1984 U.S. CODE CONG. & ADMIN. NEWS 2647, 2650. If this period of regulatory review is not marketing for the patentee, then identical activities undertaken years later by a would-be developer of newer technology cannot logically be either.[12] Petitioner and its amicus partners willingly accepted the "regulatory-review-is-not-marketing" determination by Congress in order to obtain legislative eligibility for statutory patent term extension. They cannot now make a diametrically inconsistent argument to avoid the *quid pro quo* for what they received.[13]

12. Nor could it be seriously contended that the patentee is in a different position from the years-later alleged infringer under the theory that it was a patent right, as opposed to the right to *market* during the patent term, that was being consumed by the regulatory process. Patents themselves do not provide the right to market the invention of the patent claims; they grant only the right "to exclude others" from doing so. 35 U.S.C. § 154. *That* right was not lost to the patentee during the regulatory review period, whether or not he was able to market his own version of the claimed invention during that time.

13. Similarly, petitioner's argument — that, in the case of certain long-lasting devices such as CAT scans, allowing clinical trials could substantially erode the market for the patented device — does not withstand scrutiny. In such a situation, a single machine can be used on many different patients to develop necessary data. Further, with such devices, as with drugs, there is no particular necessity that the person on whom the product is used be sick or otherwise in need of medical care. Accordingly, much testing can be performed with no affect on the market at all.

V. LOGIC AND POLICY COMPEL THE CONCLUSION THAT CONGRESS INTENDED MEDICAL DEVICES TO BE WITHIN SECTION 271(e)(1)

A. Congress' Grant Of Statutory Patent Term Extension For Medical Devices Clearly Indicates That Contemporaneously Enacted Section 271(e)(1) Also Applies To Devices

Congress' contemporaneous enactment of 35 U.S.C. § 156 and 35 U.S.C. § 271(e) and the two facets of public policy to which those sections were directed compel the interpretation that medical devices are encompassed by *both* sections. The PTR Act was intended to correct severe problems caused by the delays inherent in federal regulatory review of certain products — drugs, medical devices, and others. Section 156, the codification of the statutory extension provisions, embodies congressional recognition that regulatory delay affects not only drugs, but also medical devices.

Section 271(e)(1) was enacted with section 156 as part of the same Title II of the PTR Act to provide a balance for statutory patent term extension by allowing the same class of products as covered by section 156 to undergo regulatory testing prior to patent expiration. To limit the infringement exemption of section 271(e)(1) to drugs would destroy that balance by providing patent holders of non-drug products with the ability to delay introduction of competing technologies far beyond the expiration of even their statutorily extended patents.[14]

Congress' intention to equalize the scopes of the infringement exemption and statutory extension is reflected in the record of the committee debates. In its

14. Congressional understanding that protracted regulatory review affects devices as well as drugs is indisputably indicated by Congress' restoration of lost patent term to both. H.R. REP. NO. 857, pt. I, at 15, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2648. That same regulatory delay was the cause of the previous *de facto* extension of patents for the same products.

discussion of the constitutionality of the exemption provision, for example, the House Judiciary Committee noted:

> In this case the Committee has merely done what the Congress has traditionally done in the area of intellectual property law; balance the need to stimulate innovation against the goal of furthering the public interest.[20] Just as we have recognized the doctrine of fair use in copyright, it is appropriate to create a similar mechanism in the patent law. That is all this bill does.
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> 20 It is important to note that most patent holders affected by [35 U.S.C. § 271(e)] will also receive a benefit from the bill in the form of patent term extension. This type of exchange of property interest was upheld by the [Supreme Court] in the [*Penn Central Transp. Corp. v. New York City*, 438 U.S. 104 (1978)] case, albeit in a different context.

H.R. REP. NO. 857, 98th Cong., 2d Sess., pt. II, at 30, *reprinted in* 1984 U.S. CODE CONG. & ADMIN. NEWS 2686, 2714. The coordinated extent of the two provisions is clear. Congress balanced its stimulation of innovation (by the statutory term extension) with furtherance of the public interest (by the testing exemption and consequent elimination of de facto extension for patents relating to the same products).

The public interest that Congress intended to protect includes not only the right of the public and medical community to obtain quick access to advanced medical technology, but also the right of others to develop and to commercialize advanced medical devices as soon after expiration of the statutory patent term as possible. These aspects of the public interest would be ill-served, however, under petitioner's narrow revision of section

271(e)(1), which requires the belief that Congress intended to maintain *de facto* extensions for devices and thereby to delay public access to advanced device technology. Petitioner's position attributes to Congress the intention to confer on device patentees the benefit of statutory term extension without the requirement that they relinquish *de facto* extensions in return. It defies both logic and any reasonable view of public policy, however, to assume that Congress would set up a most privileged class of patentees entitled to both extensions when Congress so clearly recognized the detriments of *de facto* extensions. H.R. REP. NO. 857, pt. I, at 46, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2679.[15] This is not what Congress intended.

B. Implementation Of Bioequivalency Testing Procedures For Drugs In One Section Of The PTR Act Did Not Limit The Rest Of The Act To Drugs

Neither petitioner nor any amicus party has delivered on its claims that there are "persuasive reasons" why section 271(e)(1) was intended to be limited to drugs.[16] The primary "reason" advanced – that the

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15. Amici Zimmer and Bristol-Myers Squibb, in support of petitioner Lilly, argue that it is not "credible" that Congress would provide an infringement exemption "without the prompting of anyone supporting makers of generic copies of medical devices" (Zimmer and Bristol Myers-Squibb Brief, p.13). Aside from the fact that there is no class of generic device manufacturers – federal regulations provide no expedited testing procedures for mere copies of medical devices and therefore provide no impetus for the existence of such a class as they do for generic drug makers – this cynical view suggests that Congress acts only at the behest of lobbyists but not simply for the public interest. Petitioner and its supporters are simply unwilling to relinquish the consideration that Congress exacted in return for the granting of statutory extensions.

16. The Federal Circuit stated below that "no persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, particularly as medical

infringement exemption is tied to the grant of expedited bioequivalency testing for drugs – is plainly inconsistent with both the organization of the PTR Act and the undisputed effect of the enacted statutes.

Title I of the PTR Act established an expedited FDA approval procedure (for "abbreviated new drug applications," or "ANDAs") for generic equivalents of previously approved drugs. Title II of the PTR Act added section 156 to the patent laws to permit statutory extension of patents for medical devices, food additives, and color additives, as well as for drugs, all of which are subjected to FDA regulatory delays. Under that same Title II, section 271(e)(1) was enacted. Petitioner and its amici, however, would have this Court interpret section 271(e)(1) of Title II by straight analogy to the bioequivalency provisions of Title I. *See, e.g.,* Brief of Amicus Industrial Biotechnology Association, pp.16-17; Petitioner's Brief, p.29. Such a comparison is improper. There simply is no reason to interpret the scope of section 271(e)(1) in view of any title of the enacting legislation other than its own Title II. To do so here ignores the remedial balance that Title II was intended to implement when eliminating *de facto* extensions for the same scope of products for which it granted statutory extensions.[17]

In all events, the irrelevance of bioequivalency testing to the scope of section 271(e)(1) is underscored by the undisputed inclusion of certain other products

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NOTES *(Continued)*

devices receive the benefit of the companion patent term restoration legislation." *Eli Lilly and Co. v. Medtronic, Inc.*, 872 F.2d 402, 406 (Fed. Cir. 1989).

17. The House Energy and Commerce Committee stated:

> Other sections of *Title II* permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. REP. NO. 857, pt. I, at 46, 1984 U.S. CODE CONG. & ADMIN. NEWS at 2679 (emphasis added).

within the exemption that are not entitled to such expedited testing. For example, pioneer new drugs are not eligible for the expedited approval procedures enacted under Title I, but they are clearly entitled to the exemption of section 271(e)(1) for the purpose of developing data on safety and efficacy required under 21 U.S.C. § 355(b)(1) (section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act). Moreover, veterinary biological products, which were added to the exemption in 1988, are also not entitled to any expedited approval procedures under the federal law that regulates them, the Virus-Serum-Toxin Act (the Act of March 4, 1913, Pub. L. No. 62-430, 37 Stat. 832 (1913), codified as amended in 1985 at 21 U.S.C. §§ 151-59)).[18] In this regard, it is significant that these 1988 amendments to the PTR Act made veterinary biological products eligible for statutory extension under section 156 and contemporaneously eliminated *de facto* extensions for those products by adding them to section 271(e)(1) – modifying the related Title II sections of the PTR Act – *but did not authorize any expedited testing procedures analogous to the Title I provisions.* Accordingly, the argument that eligibility for bioequivalency testing somehow determines the scope of section 271(e)(1) is without merit.

Equally unimportant to the interpretation of section 271(e)(1) are the drug-specific limitations in some of the other sub-sections of section 271(e). For example, petitioner incorrectly relies on the infringement provision of section 271(e)(2), which makes it an act of infringement for a generic drug manufacturer to submit an ANDA with a requested approval date prior to patent expiration. Petitioner suggests that the absence of an analogous

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18. Veterinary biological products were added to both section 271(e)(1) and to section 156 by the Generic Animal Drug And Patent Term Restoration Act, Pub. L. No. 100-670, 102 Stat. 3971 (1988).

provision for medical devices, which would make submission of a pre-market approval application an act of infringement, is somehow evidence that medical devices are not entitled to the exemption (Petitioner's Brief, pp.17-18). This, however, ignores the fact that the submission of a New Drug Application under 21 U.S.C. § 355(b)(1) (that is, one not submitted as a generic copy of a previously approved drug) is also not designated to be an act of infringement under sub-section (e)(2), but such new drugs are undeniably included within section 271(e)(1). The attempt by petitioner and its amicus supporters to interpret section 271(e)(1) by analogy to express limitations in other sections of the statute fails.[19]

CONCLUSION

The decision by the Court of Appeals for the Federal Circuit should be affirmed. Through co-extensive sections 156 and 271(e)(1), Congress constructed a careful balance to stimulate innovation through statutory patent term extension and to further the public interest by eliminating *de facto* extensions that serve only to postpone the ability of others to advance the patentee's original contribution and therefore delay the public's access to advanced technology. That balance, and the reasons behind it, apply to all medical products. Upsetting that balance here will cause substantial harm to United States research and development efforts.

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19. Petitioner incorrectly cites and quotes out of context *Eli Lilly and Co. v. Premo Pharmaceutical Labs.*, 4 U.S.P.Q.2d 1080 (D.N.J. 1987), *aff'd*, 843 F.2d 1378 (Fed. Cir. 1988), and *Scripps Clinic and Research Found. v. Genentech Inc.*, 231 U.S.P.Q. 978 (N.D. Cal. 1986), for the proposition that sub-section (e)(2) "limits the scope of" or "qualifies" subsection (e)(1) with respect to the products that are included (Petitioner's Brief, p.17). Those cases do *not* address the question of what products are exempt, but rather what *acts* are "solely for uses reasonably related to the development and submission of information" to the FDA. The cases simply do not support the proposition for which petitioner cites them.

This Court should further confirm that there is an exception to the patentee's exclusive rights to allow making and using for experimental purposes. This exception should be broad enough to cover activities that are designed to elicit information about the patented invention and its underlying principles, whether for basic research, to develop improvements, or to design around the patent claims, and to test its sufficiency, regardless of any commercial motivation for the activities. Such an exception would encourage the efficient progress of science and the useful arts, while giving to the patentee the reward that promised by the patent system. It would encourage university research and facilitate the rapid improvement of American technology.

For all of the above reasons, amici curiae respectfully urge this Court to affirm the decision below.

Respectfully submitted,

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